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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/829,137

04/21/2004

Philip C. Gevas

ACG2BUSA

6164

270

7590

04/25/2006

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/829,137

Applicant(s)

GEVAS ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-56 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 34-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 15-29 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 07/02/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims pending are 15-56.

Response to restriction requirement filed 02/15/2006 is acknowledged. Applicant elected, without traverse, Group I, claims 15-33. Claims 34-56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Further, applicant elected proton pump inhibitors as species of an agent used together with the immunogenic composition of G17 peptide. Claims 30 is withdrawn from initial examination on merits

Claim Rejections - 35 USC § 112, first paragraph.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claim 27 is directed to use of a conjugate wherein the immunogenic composition is conjugated to both immunogenic carrier and a pharmaceutically acceptable carrier. Specification addresses conjugate with a immunogenic carrier, such as diphtheria toxin, but not a conjugate with both immunogenic carrier and a pharmaceutically acceptable carrier.

Claim Rejections - 35 USC § 102 and 103.

Claims 15-29,31-33 are rejected under 35 U.S.C.103(a) as unpatentable over admitted prior art (Background section) in view of Watson et al (Cancer Research, 1996, or Int. J. Cancer, 1995) or Gevas et al (US Patent 5,607,676).

The instant claims are directed to method for treating a mammalian subject having excess gastric acid comprising the steps of administering to said subject, (a) a proton pump inhibitor; and (b) an immunogenic composition comprising a G17 peptide of SEQ ID NO: 1 or fragment thereof.

It is well known that administering proton pump inhibitors to subjects having excess gastric acid results in hypergastrinemia, i.e., elevated level of gastrin peptides (such as G17 peptide), and that, in turn, hypergastrinemia leads to such complications as increased production of gastric acid, and gastric tumors. See Background Section, p. 1-2, or see Gevas et al, col. 1-2. Therefore, it is obvious that such side effects of proton pump blockers are undesirable and need to be treated or prevented.

Watson et al., 1995 and 1996 references, teach immunogen, Gastrimmune, which is composed of nine N-terminal residues of gastrin linked to immunogenic carrier, such as diphtheria toxoid. This composition was used in rising anti-G17 antibodies; the later reduced gastrin level *in vivo*.

Gevas et al (US Patent 5,607,676¹) teaches teach composed of G17 fragments, such as nine N-terminal residues of gastrin (e.g., col. 5, line 50), linked to immunogenic

¹as well as other US patents of these applicants (Gevas et al. are the inventors of the instant invention as well) listed in Information Disclosure Statement filed 03/20/2001.

carrier, such as diphtheria toxoid. Said immunogen generates anti-gastrin antibodies which reduce level of gastrin and inhibit hypergastrinemia related disorders.

It would be *prima facie* obvious to one of ordinary skills in the art at the time the invention was made to be motivated to use the anti-gastrin immunogen of Gevas et al or Watson et al to reduce level of gastrin and inhibit hypergastrinemia related disorders, because it would limit the side effects caused by administration of proton pump blockers.

In regard to dependent claims 16-29,31-33, if there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable conditions for treatment of patient having hypergastrinemia and subsequent side effects, and determining such parameters as order of administration, target levels of gastrin, selection of particular inhibitors, are art recognized result-effective variables which would have been routinely determined and optimized in the art.

Conclusion.


No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631